SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FEVERLET FORTE (Aceclofenac, Paracetamol and Chlorzoxazone Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Aceclofenac BP	100 mg
Paracetamol BP	325 mg
Chlorzoxazone USP	250 mg
Excipients	q.s

Colour: Quinoline Yellow

Description

A yellow coloured, oval shaped, biconvex, film coated tablet having lip breakline on one side of tablet.

3. PHARMACEUTICAL FORM

Oral Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
It is used in treatment of Pain and inflammation.
It is also used as Muscle relaxant

4.2 Posology and method of administration
Adults: 1 tablet to be taken 1 - 3 times a day after meals

Method of administration
To be taken orally**.**

4.3 Contraindications
Moderate to severe renal or hepatic impairment, Hypersensitivity, pregnancy (third trimester), severe heart failure.

4.4 Special warnings and special precautions for use
Before treatment with FEVERLET FORTE

- Alcoholic individuals, GI disease, people suffering from asthma or other allergic conditions, kidney or liver dysfunction, hypertension, cardiac impairment, hemorrhagic disorders, Pregnancy, lactation.
- The one who is on drug should remain careful while dealing with the fine activities, driving or using risky tools or machines. Doctors need to study the concerned person's Liver and kidney functions.
- Periodic blood count studies are also recommended.
- The liver enzyme levels are also studied. high levels are hazardous

4.5 Interaction with other medicinal products and other forms of Interaction
Antacids:
Paracetamol: Decreased absorption of cholestyramine within 1 hour of administration. Whereas accelerated absorption with metoclopramide.
Aceclofenac: Can increase the plasma concentration of Paracetamol: Accelerated absorption with metoclopramide. Also reduced absorption of cholestyramine within 1 hour of administration is noted.
Aceclofenac: Can increase the plasma concentrations of digoxin and lithium. Increased kidney damage with diuretics.
Serum-potassium needs monitoring when used with potassium-sparing diuretics. It can enhance anticoagulants actvity. It can increase plasma methotrexate levels which may lead to toxicity if administered soon, within 2-4 hours of methotrexate administration. High risk of convulsions with quinolones.
Chlorzoxazone: Drinking alcohol can increase certain side effects of chlorzoxazone. Other medicines that makes sleepy such as cold or allergy medicine, sedatives, narcotic pain medicine, sleeping pills, muscle relaxers, and medicine for seizures, depression, oranxiety. They can add to sleepiness caused by chlorzoxazone.
Potentially Fatal:
Paracetamol: Increased risk of liver damage if the patient is a chronic alcoholic. Increased risk of toxicity with high doses or long term admin of carbamazepine, barbiturates, hydantoins, isoniazid, rifampin and sulfinpyrazone. concentrations of lithium and digoxin. Increased nephrotoxicity with diuretics. Serum-potassium should be monitored when used with potassium-sparing diuretics

4.6 Pregnancy and lactation
Pregnancy (third trimester)

4.7 Effects on ability to drive and use machines
This medication may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

4.8 Undesirable effects
Paracetamol: Nausea, allergic reactions, skin rashes, acute renal tubular necrosis. Aceclofenac: Diarrhoea, headache, vertigo, dizzies, nervousness, tinnitus, depression, drowsiness, insomnia; fever, angioedema, bronchospasm, rashes; blood dyscrasias.

Potentially Fatal: Paracetamol: Very rare, blood dyscrasias (eg, thrombocytopaenia, leucopaenia, neutropaenia, agranulocytosis); liver damage. Aceclofenac: Severe GI bleeding; nephrotoxicity.

Chlorzoxazone:
Black, bloody, or tarry stools;
Nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools,

jaundice (yellowing of the skin or eyes);
coughing up blood or vomit that looks like coffee grounds; or feeling like you might pass out.

4.9 Overdose
If the drug overdose happens' gastric lavage or enema is used to empty the stomach as soon as possible. Symptomatic treatment is started as per the need Overdose symptoms may include nausea, vomiting, diarrhea, drowsiness, dizziness, headache, muscle weakness, shallow breathing, or fainting.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code:
Aceclofenac: M01AB16
Paracetamol:N02BE01
Chlorzoxazone:M03BB0

Aceclofenac is a phenylacetic acid derivative that inhibits synthesis of the inflammatory cytokines interleukin-1b and tumour necrosis factor, and inhibits prostaglandin E2 production. It increases glycosaminoglycans (GAG) synthesis, the principal macromolecule of the extracellular matrix, which aids in repair and regeneration of articular cartilage.
Thus, aceclofenac has +ve effects on cartilage anabolism combined with modulating effect of matrix catabolism.
Paracetamol has analgesic and antipyretic action with weak anti-inflammatory activity.
It produces analgesia by increasing pain threshold and antipyresis by acting on the hypothalamic heat-regulating centre Chlorzoxazone, a synthetic compound, inhibits antigen-induced bronchospasms and, hence, is used to treat asthma and allergic rhinitis. Chlorzoxazone is used as an ophthalmic solution to treat conjunctivitis and is taken orally to treat systemic mastocytosis and ulcerative colitis. Chlorzoxazone is also a centrally-acting agent for painful musculoskeletal conditions. Data available from animal experiments as well ashuman study indicate that chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex a.c. involved in producing and maintaining skeletal muscle spasm of varied etiology. The clinical result is a reduction of the skeletal muscle spasm with relief of pain and increased mobility of the involved muscles.

5.2 Pharmacokinetic properties
Aceclofenac:
Aceclofenac is a phenylacetic acid derivative that inhibits synthesis of the inflammatory cytokines interleukin-1b and tumour necrosis factor, and inhibits

prostaglandin E2 production. It increases glycosaminoglycans (GAG) synthesis, the principal macromolecule of the extracellular matrix, which aids in repair and regeneration of articular cartilage. Thus, aceclofenac has +ve effects on cartilage anabolism combined with modulating effect of matrix catabolism. Paracetamol has analgesic and antipyretic action with weak anti-inflammatory activity. It produces analgesia by increasing pain threshold and antipyresis by acting on the hypothalamic heat-regulating centre.

Absorption

Aceclofenac: Rapidly absorbed; almost 100% bioavailability; peak plasma levels reached about 1.25-3 hours after oral admin.

Distribution

Aceclofenac: >99.7% bound to plasma proteins; distributes into synovial fluid.

Paracetamol: Distributes throughout most fluids of the body.

Metabolism

Aceclofenac: Probably metabolised by CYP2C9; average plasma elimination half-life: 4-4.3 hours. Paracetamol: Mainly metabolised hepatically; plasma elimination halflife: 1-4 hours.

Excretion

Aceclofenac: About two-thirds of the administered dose is removed in the urine, mainly as conjugated hydroxymetabolites. Paracetamol: Most metabolites are removed in the urine within 24 hours.

Paracetamol

Absorption:

Paracetamol is readily absorbed from the gastrointestinal tract.

Distrubution:

peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Metabolism:

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Elimination:

It is excreted in the urine, mainly as the glucuronide and sulphate conjugates. The elimination half-life varies from about 1 to 4 hours.

Chlorzoxazone

Absorption- Rapidly and completely absorbed after oral administration.

Distribution- Widely distributed in the body.

Metabolism- It is metabolized in the liver to its metabolites by glucoronide conjugation.

Excretion- It is excreted through urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Raw Material	Pharmacopoeia
1.	Sodium Lauryl Sulphate	BP
2.	Maize Starch	BP
3.	Fumaric Acid	IHS
4.	Purified Water	BP
5.	Hydroxypropyl Cellulose	BP
6.	Purified Talc	BP
7.	Croscarmellose Sodium	BP
8.	Colloidal Anhydrous Silica	BP
9.	Sodium Stearyl Fumarate	USP NF
10.	Sodium Metabisulphite	BP
11.	Hypromellose	BP
12.	Isopropyl Alcohol	BP
13.	Dichloromethane	BP
14.	Titanium Dioxide (Color Code Index:77891)	BP
15.	Diethyl phthalate	BP
16.	Colour Quinoline yellow (Colour code index: 47005)	IHS

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30^0 C. Protect from light & moisture.

6.5 Nature and contents of container

12 Tablets in Alu / PVC Blister & 1 such Blister in a carton = 1 x 12's = 12 Tablet's

6.6 Instructions for use and handling

No special requirements

7. Marketing Authorisation Holder

Aurochem Laboratories (India) Pvt. Ltd.
333, Gundecha Industrial Complex, 3rd Floor, Akurli Road.
Kandivali (E), Mumbai - 400101,
India.
Tel: +(91)-(22)-2885 8503/04/05
Fax: +(91)-(22)-2887 3236
E-mail: info@aurochemgroup.com
website: www.aurochemlaboratories.com

8. Marketing Authorisation Number (S)

Form 25A in KD/771-A

9. Date of First Authorisation/Renewal of the Authorisation

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10. Date of Revision of the Text

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11. Name and Address of Manufacturer

Aurochem Laboratories (India) Pvt. Ltd.
At Plot no.58, Palghar Taluka,
Ind Co-Op Estate Ltd. Boisar road,
Tal-Palghar, Thane – 401 404,
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